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SIPDIS

HHS FOR OGHA - STEIGER, ELVANDER, BHAT

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TAGS: [EAGR](#) [KIPR](#) [SENV](#) [TBIO](#) [TH](#)

SUBJECT: THAIS PLAN FOR TAMIFLU PRODUCTION

1. Summary: The RTG is actively stockpiling the antiviral medicine Tamiflu and considering producing the drug in Thailand, with or without a license, in preparation for a possible avian flu pandemic. The RTG is procuring ingredients for production of the drug, but it is unclear if the Thai pharmaceutical industry could produce a sufficient supply of the drug, or whether they would have the technical skill to produce it without assistance from the original producer. Thailand's thirteenth confirmed human death from avian influenza, the first in just over a year, will likely increase local interest in the issue of antiviral medication availability. End Summary.

2. The RTG Ministry of Public Health (MoPH) has set a goal of amassing a stockpile of one million capsules of the Swiss pharmaceutical company Roche's antiviral medicine Tamiflu by the end of January, 2006. MoPH claims to have 700,000 capsules on hand and is working to acquire an additional 300,000. An individual treatment of Tamiflu is considered to be ten capsules, meaning MoPH's planned stockpile would be sufficient to treat 100,000 people. MoPH is also discussing with Roche to purchase Tamiflu in powder form which has a longer shelf life than capsules and would be easier to administer if a pandemic did occur. The powder form would not need approval by the Thai Food and Drug Administration as the ingredients are the same as the capsule form.

3. Dr. Thawat Sungrajarn, director general of the Department of Disease Control, made comments to the press that the RTG was prepared to issue a compulsory license of the drug in order to begin production without a license from Roche. However, the Department of Intellectual Property's Patent Office which has responsibility for compulsory licenses had not received any word that such a proposal was being considered.

4. Mr. Robert Mitchell, Managing Director of Roche in Bangkok, said that his firm had been in discussions with MoPH about importing large quantities of Tamiflu, but that no RTG official had mentioned to him a possible move to pursue compulsory licensing and was surprised by the news accounts. In fact, according to Roche, Gilead Sciences, the original right holder for the drug, never filed a patent for Tamiflu in Thailand and the drug remains unpatented.

5. Mitchell said there had been discussions with the RTG regarding manufacturing the drug in Thailand, but that it was too early to say where those discussions could lead. Mitchell was somewhat dismissive of the Thai intention to produce the drug, saying that the RTG could purchase substantially greater quantities than they could ever produce on their own.

6. The Government Pharmaceutical Organization (GPO) is the lead drug manufacturer in Thailand and would produce any Thai version of Tamiflu. GPO claims they can develop the drug and produce 50,000 treatments by October, 2006, at a cost 40% below the purchase price from Roche. MoPH said they have already ordered precursor ingredients from a supplier in India.

7. Prime Minister Thaksin Shinawatra announced on October 20 Thailand's thirteenth confirmed human death from avian flu, the first since October 8, 2004. The man died one day earlier in Kanchanaburi province, about 150 kilometers west of Bangkok, after slaughtering and eating poultry that had apparently died from avian flu. His eleven year old son is currently hospitalized in Bangkok with similar, but less severe, symptoms.

8. Comment: Despite RTG claims that they could produce a substantial supply of Tamiflu within a year, with or without a license, it is unclear if GPO has the capability or the capacity to produce Tamiflu in sufficient quantity. Roche has said publicly that the production process consists of a complicated ten-step procedure, some of which are time consuming and at least one step is quite difficult, involving volatile or dangerous compounds. GPO has had success reverse engineering and producing other drugs, but without direct assistance from Roche under a licensing agreement, production of a generic form of Tamiflu could prove a difficult venture. End Comment.

BOYCE